THE FUTURE OF QUALITY ASSURANCE IN HEALTH CARE: NEXT STEPS FROM THE PERSPECTIVE OF THE FEDERAL GOVERNMENT*

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BEING the final speaker at this important meeting gives me the opportunity to end on an optimistic note. I must admit, however, that I have aged considerably while listening to Professors Eli Ginzberg and Selma Mushkin. I hope that we can learn from their cautionary advice and avoid some of the hazards they foresee.

Today, in 1975, I think it is fair to say that quality assurance, for good or bad, is here to stay. The issue is not whether quality assurance will be required, but how we can make it work for all—consumers, providers, and payors of health-care services. Despite Professor Ginzberg's skepticism, I remain convinced of the potential of the Professional Standards Review Organization (PSRO) concept and am already impressed that it has stimulated leadership in many sectors of the health-care community.

I would like to offer my speculations on the future of quality assurance in health care from the perspective of the federal government. A brief survey of current activities and trends in quality assurance provides the needed grounding in reality for such speculation. It is to be hoped that any preparation for the future by governmental or private organizations will be based on insights acquired from a careful analysis of past and current programs.

Traditionally, the medical profession has always had a major interest in the issue of quality. But during the past 20 years there has been a substantial increase in the number and scope of organized programs of quality assurance. A number of other trends also have become evident:

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1) The nature of quality assurance has shifted from a predominantly voluntary to a required activity.

2) There has been a change in emphasis from assessment of the structure of medical care to assessment of the actual process of giving care and the outcome of that care.

3) There has been a gradual extension of organized quality-assurance activity from the acute-care hospital setting to the long-term-care and ambulatory settings.

4) Quality assurance has moved from a part-time, episodic, and largely internal staff-committee function to a full-time, external, and ongoing responsibility, with organizations established primarily for the purpose of conducting peer review.

While many factors have contributed to these trends, probably the most important have to do with the rapid increases in total expenditures for health care, the growing proportion of health-care services financed out of government funds, and the resultant pressure to assure the quality of the services being purchased. Any future movement toward even broader coverage under national health insurance will accelerate this pressure. In such circumstances, an understanding of the history of quality assurance is critical if we are to predict more accurately the impact of future change on current trends.

With the establishment of the Joint Commission on the Accreditation of Hospitals (JCAH) in the 1950s, quality-assurance became entrenched as a major ongoing aspect of the delivery of health care in the United States. Accreditation by JCAH is voluntary. Today, almost two thirds of the more than 7,000 short-term hospitals in the United states are accredited. Other formal and informal voluntary mechanisms of quality assurance also are a routine part of American medicine. The formal mechanisms include specialty boards, grand rounds, clinical pathological conferences, and a multiplicity of programs of continuing medical education. Among the more common informal mechanisms are clinical consultations, curbside consultations, and a broad range of self-testing and improvement programs in which many health professionals now participate on a regular basis.

With the enactment of Medicare in 1965, quality assurance moved from a voluntary activity to a required one. As a prerequisite to payment under the major government-sponsored programs of health delivery and financing, providers of services are required to comply with

standards of quality assurance and conditions of participation. Initially, all hospitals which were accredited by the JCAH were deemed to comply with governmental standards of quality, and federal standards were precluded from being any higher than those of the JCAH. In 1972 Congress freed government standards from this restriction and required the Department of Health, Education, and Welfare to establish an ongoing program to validate the JCAH process of accreditation.

Medicare also changed the focus of quality-assurance programs from a structural orientation to a concern with process and outcome. Its requirements for utilization review (UR) crystallized this change. Although they initially provoked a cost-quality controversy, with subsequent changes, particularly the addition of requirements for medical-care evaluation studies, UR became one of the major quality-assurance mechanisms.

Medicare's conditions of participation and JCAH accreditation primarily focus on an institution's structural capability to provide quality medical care. This is a proxy measure based on the assumption that an adequate physical plant, qualified personnel, and an effectively organized and administered facility will provide quality services.

Measurements of process and outcome assess the actual care-giving process and the results of health-care services. The PSRO program represents the most recent and dramatic example of this approach. Through the use of explicit criteria and the peer-review process, the PSROs attempt to assure and improve quality by identifying deficiencies in health-care practices and correcting them through continuing education.

Under Medicare, UR also extended requirements for review from the hospital setting to other institutional settings. The interest in long-term care, especially in nursing homes, during the last several years has helped to precipitate this trend. Repeatedly, the process of quality assurance has been called upon, perhaps inappropriately, to correct fundamental problems in long-term care.

Interest in ambulatory-care review also has increased substantially. Many state Medicaid programs operate ongoing ambulatory-review programs. The Experimental Medical Care Review Organization program has sponsored a variety of demonstration projects on outpatient review, and the new Health Maintenance Organization (HMO) legislation requires organized providers who are receiving benefits under

the act to assure the quality of the ambulatory care they provide.

Passage of the Bennett Amendment in 1972 marked the beginning of a change in focus for quality-assurance programs from an activity of internal committees to an external function. The congressional interest in creating PSROs was to take advantage of effective internal review and supplement it by transferring the responsibility for quality assurance to a more objective level, thereby establishing a degree of accountability which was not possible under the pre-existing fragmented review programs. PSROs will be conducting reviews by next year in about one third of the United States. They are community-based physician organizations which contract directly with the federal government to perform professional review and assure the quality of the services provided to beneficiaries of Medicare, Medicaid, maternal and child health, and crippled children's programs. Although the initial emphasis of the program is on hospital review, PSROs are planning to extend their scope to include long-term care, ambulatory services, and patients whose care is financed through private programs such as Blue Cross, Blue Shield, and commercial insurance companies.

The major issue of quality assurance for the future is the need to prepare for national health insurance and, prior to that, for the review by PSRO of additional care which is not federally funded. The quantitative aspects of this challenge are staggering—30 million hospital episodes, almost a million nursing-home admissions, and up to a billion outpatient transactions per year. This, coupled with the serious methodologic issues yet to be resolved and the limitations of our present capabilities, make the task a tremendous one, for which we come prepared with only a limited amount of experience. Those of us in the federal government who are charged with implementing the PSRO program on a national scale are acutely aware of these problems.

Challenges for the Future

An examination of past trends and already known requirements allows us predict some of what we must be prepared for in the future. We must develop the capacity to provide effective quality assurance for all patients during the next decade, in conjunction with making expanded services available to all citizens. A number of critical challenges must be met if we are to achieve this objective. These challenges must be addressed in a reasonable, coordinated manner if we are to

succeed in developing our goal of an effective review system for all patients in all settings. This cannot be accomplished by continuing the current piecemeal system; rather, we must develop a new, integrated and more efficient system.

Our most immediate and perhaps overriding need is to develop a national strategy. This strategy must combine research, demonstration, training, and evaluation activities. It must define the major problems to be addressed over the next several years, the methods by which these problems will be addressed, the priorities which must be assigned, and the expected outcomes of our developmental efforts. It must not only address broad questions of policy dealing with quality review, but also a number of subsidiary technical questions which are of equal importance.

In conjunction with the research and development component of our national strategy, we must perform ongoing evaluation of the developmental and operational efforts which we shall be carrying out. In-depth evaluation is an immediate priority. Effective methods of evaluation must be designed to identify those procedures and approaches which prove most effective to translate them into accepted methods of quality review with as little delay as possible.

This national strategy is important. Its development will require increased attention from many public and private leaders. In this time of shortage of resources, it is needed urgently to prevent waste and to direct the limited talent and funds which are available toward the priority issues. While such a long-range strategy is being defined, a number of activities need to be pursued.

First, the development, testing, and implementation of a community-wide system for quality assurance is needed. In order to do this, an organizational infrastructure is required around which community review programs can be established and maintained. I hope that the PSRO can begin to play this nuclear role, establishing review programs not only in the hospital but in long-term-care facilities and ambulatory settings as well. As we build this model, it will be necessary to develop effective continuing linkages between the components of the system. This will be important in order to ensure the required cross-component review capability which is essential.

The operation of such a model depends upon links that relate services between the components and a base of integrated information drawn from all components of the system, and available to all compo-

nents and to others concerned with effective delivery of health services. In this model, data is collected from all providers of care and is aggregated across all health-care financing programs to allow the creation of comprehensive profiles for review. The analyses of such data may be limited to one institution, may encompass a number of institutions, or may include both institutional and noninstitutional care. To handle such a tremendous volume of information, reliance must be placed on the use of norms, criteria, and standards as initial screening parameters. In addition, the topics of analytic study must be defined clearly and patients whose care is to be audited must be selected efficiently.

In developing such a community-wide system or model, we should make every effort to avoid developing a rigid approach to quality review. Rather, our intent should be to develop an over-all framework around which local modifications can be made. These local modifications are necessary to reflect the specific needs and practices of the environment in which health services are provided and in which any review will be conducted. This model represents an ideal. I have no doubt that such a system is needed and that it can be developed, but this should be done one step at a time. Each component of the model needs to be tested before an integrated community-wide quality-review system can be established.

Second, we need to improve our capabilities for collecting and processing data so that we shall be able to link the dynamic elements of review. This is perhaps one of our most important challenges and certainly one of the most difficult to meet.

Third, we must use the results of our quality-assurance studies to develop procedures which will improve the outcome of health care for patients. Our goal is to achieve definitively improved health status for the entire population. We cannot attain this goal through the review of claims one by one. Rather, the attainment of this goal is predicated on the development of methodology for the conduct of ongoing, efficient studies to evaluate medical care; these studies should define the problems in the process of care which are impeding the attainment of improved health status and specify the actions needed to correct these problems. Improved outcomes of health care will of course require changes in other areas of the patient's life besides the provision of health-care services. The patient's life style and socioeconomic status are often at least as important to the outcome of health care

as is the quality of the health-care services which are provided.

Fourth, we must develop effective methods for reviewing ambulatory care. In addressing the review of ambulatory care, a wide range of problems must be overcome. First and foremost, we must decide how to select appropriate samples of ambulatory services for review, given the volume of services which are provided annually. Our task is to identify those services and practices which require review, to determine under what conditions they require review, and to decide how this review is to be conducted.

As we prepare for the future, we must not forget that a substantial base of experience already exists. It is neither necessary nor reasonable that we start *de nova*. Rather, we must build upon what has already been accomplished, examine and reexamine the trends we spoke of earlier, interpret their meanings, define the questions which remain to be answered, and then answer them as rapidly as possible. At this time our major emphasis should be to move the process of review to a point of maturity in a planned and reasonable manner. In so doing, we must keep in mind several underlying principles: 1) We must eliminate the rigidity and red tape which surrounds many of our present review systems. 2) We need to reduce our use of costly methods of review; we should accept only those review mechanisms which have proved effective at a reasonable price. 3) We need to reduce our reliance on quality assurance as a mechanism to reduce costs. In the long run, an effective quality-assurance system may help to meet this objective. However, effective quality assurance cannot be concerned principally with the control of costs. We must recognize that an effective system of quality assurance will both increase and reduce certain costs over time and we must be prepared for short-term increases in certain areas in order to attain our broader objectives.

Concluding Comments

In concluding these remarks about the future of quality assurance I would like to recall how far quality assurance in this country has come. Our experience in the past 20 years has established several important principles.

First, we have come to recognize that effective quality assurance cannot be mandated from on high. Rather, it must originate locally as a result of direct action by the medical community. The federal gov-

ernment can provide the framework and tools to facilitate the efforts, but the real work must be done at the community level. Second, to be successful, such an approach must be based upon a series of positive incentives which involve much interaction between the continuing educational and review systems. Third, a good system of quality assurance should recognize the distinction between cost control and efforts to improve quality.

Today (and tomorrow as well, as Professor Mushkin indicated) the public is demanding increasingly that the health services which they receive be of the highest quality we can provide—regardless of who pays the bills. Increasingly, they are able to perceive when health services are not of that high quality. The health professions in the United States are fortunate in that they have adequate tools and knowledge to provide the best quality care available anywhere. Our task must be to assure that these tools and this knowledge are used to their best advantage to meet the challenges of the future.

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